

# **Etrasimod**

This information is for people with Ulcerative Colitis who are taking etrasimod, also known as Velsipity. It is also for anyone who is thinking about starting treatment with etrasimod. Our information can help you to decide if this treatment is right for you. It looks at:

- How the medicine works
- What you can expect from the treatment
- Possible side effects
- Stopping or changing treatment

This information should not replace advice from your healthcare professional. Talk to your IBD team or read the leaflet that comes with your medicine for more details. You can also find out about your medicine at <a href="medicines.org.uk">medicines.org.uk</a>.

Etrasimod is not currently recommended for people with other forms of Inflammatory Bowel Disease, such as Crohn's Disease or Microscopic Colitis. Where we use the term 'Colitis' in this information we are referring to Ulcerative Colitis.

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# **Key facts about etrasimod**

- Etrasimod is used to treat Ulcerative Colitis in people aged 16 and over. It can help get your symptoms under control and keep them under control.
- Etrasimod is a tablet that is taken once a day.
- Etrasimod may be used if other medicines have not worked well to control your symptoms. It may also be used if you cannot take other medicines for Colitis.
- Etrasimod can affect your immune system. You may be more likely to get an
  infection, while you are taking etrasimod. If you have any concerns about infections,
  talk to your IBD team.
- Etrasimod should not be used if you are pregnant, planning on becoming pregnant, or breastfeeding.
- There is not currently any evidence on whether it's safe to have any vaccines while taking etrasimod.

## Other names for this medicine

Etrasimod is also known by the brand name Velsipity.

## What is etrasimod and how does it work?

Etrasimod is a type of medicine called a sphingosine-1-phosphate, or S1P, receptor modulator. Etrasimod attaches to proteins on lymphocytes, a type of white blood cell. This stops lymphocytes from travelling around the body. Lymphocytes help to fight infections but can sometimes cause problems. Some people with Colitis may have too many lymphocytes in their gut, which causes inflammation. Etrasimod stops lymphocytes from reaching the gut and eases the symptoms of Colitis.



## Why you might be offered etrasimod

Etrasimod is used to treat people aged 16 years or older who have moderately to severely active Colitis. The aim of this treatment is to get your Colitis under control and keep it under control. Your IBD team may suggest etrasimod if you:

- Cannot have standard treatments or biologic medicines
- Did not respond well enough to standard treatments or biologic medicines
- Have stopped responding to standard treatments or biologic medicines

Standard treatments include <u>5-ASAs</u>, <u>steroids</u>, <u>azathioprine</u> and <u>mercaptopurine</u>. <u>Biologics</u> include adalimumab, golimumab, infliximab, risankizumab, ustekinumab and vedolizumab.

Other treatments for Ulcerative Colitis include JAK inhibitors, such as tofacitinib, filgotinib and upadacitinib, and other sphingosine-1-phosphate receptor modulators, such as ozanimod.

See our resource on treatments for more information.

Different medicines work for different people. It can take time to find the medicine that works for you.

# **Deciding which medicine to take**

You may have been given a choice of taking etrasimod or a biologic medicine. Our information on medicines for Crohn's and Colitis can help you decide.

There are lots of things to think about when you start a new medicine. Your IBD team will talk to you about your options. For new medicines, you might want to think about the aim of the treatment and what the pros and cons might be. Some things to think about include:

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- How you take it
- How well it works
- How quickly it works
- Possible side effects
- Whether you need ongoing tests or checks
- Other medicines you are taking
- Other conditions you have
- If you are planning to get pregnant or breastfeed in the next few years
- What happens if you don't take it

Other treatment options that might be considered instead of etrasimod, include:

- Biologics
- <u>Tofacitinib</u>
- <u>Upadacitinib</u>
- Filgotinib
- Ozanimod

You could use our <u>medicine tool</u> to help you think about your options. Our <u>appointment</u> <u>guide</u> also has a list of questions you might want to ask your IBD team. We also have information on other <u>medicines</u> or <u>surgery for Colitis</u>.



#### **How well does etrasimod work in Colitis?**

At first, etrasimod is used to get your Colitis symptoms under control. This is called induction. Once your Colitis is under control, etrasimod aims to keep it under control. This is called remission.

Find out more about how we talk about the effectiveness of medicines.

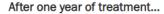
Etrasimod does not work for everyone. But it can be helpful for some people. Etrasimod may work better in people who haven't previously taken other medicines. This includes biologic treatments, or medicines like tofacitinib, upadacitinib and filgotinib.

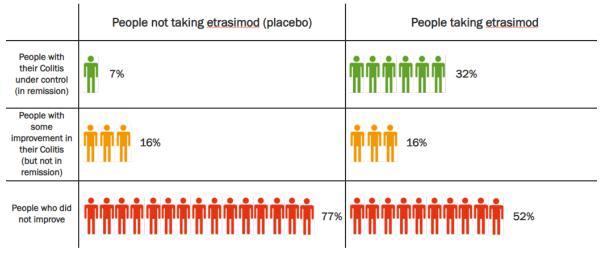
There have been two clinical trials that have looked at how well etrasimod works. These trials included adults with moderate to severely active Colitis. The people in the trials were given etrasimod or a placebo. A placebo is a substance that looks the same as the treatment but does not have any medicine in it. Comparing etrasimod to a placebo helps us see how effective it is. The people in the trials did not know whether they were taking etrasimod or a placebo.

The table below represents how many people were in remission after a year of taking etrasimod compared to a placebo. 433 people were involved in this trial. 289 took etrasimod and 144 took placebo.

After one year of treatment, 32 in every 100 people who took etrasimod were in remission. Of the people who took placebo, 7 in every 100 were in remission.







Etrasimod has not been directly compared with other medicines in clinical trials.

## How quickly etrasimod works

Everyone responds differently when taking a new medicine. Some people start to feel better after taking etrasimod for about two weeks, but it may take longer. Some people might not respond at all.

#### How to take etrasimod

Etrasimod is a tablet that is taken once a day. The same dose of etrasimod is given to everyone. Etrasimod should be swallowed whole and not crushed or chewed. For the first three days of starting etrasimod, it should be taken with food. This is to reduce the chance of side effects, such as your heart rate lowering. After the first three days, etrasimod can be taken with or without food.

If you miss one dose of etrasimod, take your next dose at your normal time. You should not take a double dose.



If you have stopped taking etrasimod for a week or longer, take it with food for three days if you start again. Let your IBD team know if you have stopped taking etrasimod for a week or longer.

Etrasimod does not need to be stored in any special conditions.

## How long will I be on etrasimod?

Your IBD team will discuss with you how long you will take etrasimod for.

## **Stopping or changing treatment**

There are a few reasons you or your IBD team might think about stopping or changing etrasimod. These include if you experience side effects, or if etrasimod does not work for you.

You should have regular checks to see how etrasimod is working for you. If it is not working well, your IBD team might suggest a different treatment.

You have a right to take part in decisions about your treatment. Tell your IBD team what matters most to you. This will help them give you the information and support you need. Our <u>appointment guide</u> can help you have these conversations. You should not stop taking etrasimod without letting your IBD team know.

# **Taking etrasimod with other Colitis treatments**

Your IBD team will let you know if you need to take other medicines alongside etrasimod. Your doctor may ask you to stop taking some of the medicines you take for your Colitis. But you may continue taking medicines like steroids or 5-ASAs.



## **Checks before starting this medicine**

Your IBD team will check if etrasimod is right for you. This will involve asking about any pre-existing conditions and having some tests.

## **Pre-existing conditions**

Tell your IBD team if you:

- Have any allergies.
- Have a weakened immune system
- Have had a heart attack or you've experienced unstable angina, a type of chest pain, in the last six months
- Have had a stroke or mini stroke, also called a TIA or transient ischaemic attack, in the last six months
- Have heart failure
- Have an irregular or abnormal heartbeat
- Have hepatitis, an infection in your liver
- Have tuberculosis, also known as TB
- Currently have cancer
- Have severe liver damage
- Are pregnant, or are not using effective contraception and could get pregnant
- Have severe lung disease. For example, pulmonary fibrosis, asthma or chronic obstructive pulmonary disease (COPD)
- Have macular oedema. This is a build-up of fluid in part of your eye, causing blurred vision



- Have diabetes
- Have a history of eye inflammation, also known as uveitis
- Take any other medicines

Etrasimod might not be the best choice for you if any of these situations apply. Talk to your IBD team to find out what your options are.

## **Blood tests**

Before starting etrasimod you will have some blood tests. They should include:

- Full blood count. Some people who take etrasimod develop low levels of lymphocytes, a type of white blood cell. Your IBD team will check your lymphocyte levels before starting treatment.
- Liver function tests. Some people who take etrasimod develop changes in liver enzymes. Your IBD team will check your liver enzymes before starting treatment.

Read more about these blood tests in our information on tests and investigations.

## **Eye checks**

Etrasimod can cause a condition called macular oedema. This can cause blurred vision. People with diabetes or pre-existing eye conditions are more likely to get macular oedema. Let your IBD team know if you have diabetes or have had previous problems with your eyes.

Everyone who is starting etrasimod should have an eye test. The NHS website provides information on who can get <u>free eye checks</u>.

## **Heart monitoring**

Etrasimod can cause a temporary slow heart rate. In clinical trials, some people had a low heart rate on the day of, or day after taking etrasimod. Before starting etrasimod you

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will need to have an electrocardiogram, known as an ECG. This is a quick and painless test that looks at how your heart is working. An ECG will help look for any heart problems.

If you already have a slow heart rate or certain heart conditions, you will be monitored for at least four hours after taking your first dose. Monitoring may include an ECG before and four hours after taking etrasimod. You may also have hourly checks of your pulse and blood pressure. If you need monitoring, you will take your first dose of etrasimod in hospital.

# **Ongoing checks**

Your IBD team will check how well etrasimod is working. You may need to have a camera put into your mouth or bottom, called an endoscopy. You might also need a poo test, called a faecal calprotectin test.

You can also expect to have:

- Liver function blood tests. These will happen one, three, six, nine and twelve months after starting etrasimod. After a year, you will continue to have tests every now and then.
- Regular blood pressure checks
- Full blood count blood tests. These will happen every now and then for as long as you take etrasimod.

If you have diabetes or pre-existing eye conditions, you will also need regular eye checks. Talk to your IBD team about how often you will need these.

# **Special precautions**

#### **Skin cancer**



Etrasimod belongs to a group of medicines called sphingosine-1-phosphate, or S1P, receptor modulators. There have been some reports of a very small number of people developing skin cancer after taking these kinds of medicines. You should not undergo any light therapy, known as phototherapy, if taking etrasimod.

Use suncream to protect yourself against the sun. Let your GP or IBD team know if you notice any changes to your skin.

The NHS website has more on staying safe in the sun.

### **Progressive Multifocal Leukoencephalopathy**

Progressive Multifocal Leukoencephalopathy, also known as PML, is a rare brain infection. PML has been reported in a very small number of people taking medicines that are similar to etrasimod. Symptoms of PML include:

- Changes in the way you see
- Becoming increasingly weak
- Clumsiness
- Memory loss
- Confusion

If you develop any of the symptoms of PML contact your IBD team urgently. If you can't contact your IBD team, ring 111 or go to A&E.

## **Posterior Reversible Encephalopathy Syndrome**

Posterior Reversible Encephalopathy Syndrome, also known as PRES. PRES is a condition where parts of the brain are affected by swelling. PRES has been reported in a



very small number of people taking medicines that are similar to etrasimod. Symptoms of PML include:

- Severe headache
- Confusion
- Fits, also known as seizures
- Loss of vision

If you develop any of the symptoms of PRES contact your IBD team urgently. If you can't contact your IBD team ring 111 or go to A&E.

### **Side effects**

All medicines can have side effects, but not everyone gets them. Having certain side effects might mean that etrasimod is not right for you.

- Some side effects can happen right away. Others may happen after you have been taking etrasimod for a while.
- Some side effects are mild. Others may be more serious and could need treatment.
- Some side effects may go away on their own. Others may go away after you stop taking etrasimod. Some may be long lasting.

Because etrasimod is a new medicine there is not a lot of evidence on long-term side effects.

Speak to your IBD team if you experience any side effects.



#### **Possible serious side effects**

#### **Infections**

Etrasimod can affect the way your immune system works. You may be more likely to get an infection while you are taking etrasimod, and for up to two weeks after you stop taking it. In addition, any infection you already have may get worse.

Contact your IBD team straight away if you think you might have an infection.

Signs of an infection include:

- A high temperature.
- Flu-like symptoms.
- Coughing and feeling tired or short of breath. This could be a sign of pneumonia.
- Peeing more than usual, or a burning feeling when you pee. This could be a sign of a urine infection.
- A severe headache with a stiff neck. This can be a sign of meningitis. You might also be sensitive to light, feel sick, have a rash, be confused, or have seizures.
- Sore, red skin or a painful skin rash with blisters. This could be a sign of shingles.

Our information on <u>immunosuppressant precautions</u> has tips on what you can do to reduce the risk of infection.

#### **Allergic reactions**

Some people may be allergic to the ingredients in etrasimod.

Call 999 if you think you are having a severe allergic reaction.

Signs of a severe allergic reaction include:

- Your lips, mouth, throat or tongue suddenly becoming swollen
- Your throat feeling tight

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- Struggling to breathe, or breathing very fast
- Becoming very confused, drowsy or dizzy
- · Fainting and not being able to be woken up
- A swollen, raised or itchy rash

## **Very common side effects**

Very common side effects can affect more than 1 in 10 people. These may include lower levels of a type of white blood cell called lymphocytes. Having a low lymphocyte count does not always cause symptoms. But it can increase your risk of infection. See <a href="infections">infections</a> for signs that you should watch out for. In most people lymphocyte levels go back to normal around one to two weeks after stopping etrasimod. If your lymphocyte levels get too low, your IBD team may stop etrasimod.

#### **Common side effects**

Common side effects can affect between 1 in 10 people to 1 in 100 people. These may include:

- Infections of your lungs or urine infections
- Low levels of a type of white blood cell called neutrophils
- High cholesterol
- Headache
- Dizziness
- Blurred vision
- Slow heart rate
- High blood pressure
- Increased liver enzyme levels in blood tests

Changes to your liver enzymes can sometimes cause other symptoms. These include:

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- Yellowing of the skin or eyes
- Brown urine
- Right sided tummy pain
- Tiredness
- Loss of appetite
- Feeling sick or vomiting

Contact your IBD team straight away if you develop any of these symptoms.

#### **Uncommon side effects**

Uncommon side effects can affect between 1 in 100 people to 1 in 1,000 people. The uncommon side effects of etrasimod include:

- Blurred vision due to a condition called macular oedema. Early macular oedema can be reversible.
- Heart block. Heart block is when the heart beats slowly or in a way that it doesn't
  normally. This happens because of problems with electrical pulses that control
  how your heart beats. Heart block that is seen after taking etrasimod tends to be
  reversible.

This is not a full list of side effects. For more information see the Patient Information Leaflet that comes with your medicine. You can also download the leaflet by searching for 'etrasimod' on the <u>Electronic Medicines Compendium (EMC)</u>.

We encourage you to report any side effects to the Medicines and Healthcare Products Regulatory Agency (MHRA). You can do this through the <u>Yellow Card scheme online</u> or by downloading the MHRA Yellow Card app (<u>yellowcard.mhra.gov.uk</u>). This helps collect important safety information about medicines.



# **Taking other medicines**

Tell your IBD team about any other medicines you are taking or thinking of taking. This includes:

- Prescribed medicines
- Over-the-counter medicines
- Multi-vitamins or supplements
- Herbal, complementary or alternative therapies

Tell your doctor or pharmacist if you take, or have recently taken:

- Medicines that control your heart rate and blood pressure. This includes beta blockers and calcium channel blockers
- Medicines to control your heartbeat or any abnormal rhythms
- Medicines that affect your immune system
- Fluconazole, which is an anti-fungal medicine
- Rifampicin, which is an antibiotic
- Enzalutamide, which is a hormone drug
- Any vaccinations

## **Vaccinations**

It is recommended that you make sure you are up to date with vaccines before starting etrasimod.

There is not yet any data on whether vaccines are safe in people taking etrasimod. Vaccines might be less effective if you're taking etrasimod. Talk to your IBD team about whether you should have the annual flu and Covid booster vaccines.

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#### **Live vaccines**

You should avoid any live vaccines whilst taking etrasimod. You should not have live vaccines for at least two weeks after stopping etrasimod.

Live vaccines contain weakened live strains of viruses or bacteria. You should not have live vaccines if you are immunosuppressed. This is because the weakened virus could reproduce too much and cause a serious infection. In the UK, live vaccines include:

- Rotavirus vaccine: babies only
- Measles, mumps and rubella vaccine, also known as the MMR vaccine either as individual vaccines or as the triple MMR vaccine
- Nasal flu vaccine used in children: the injected flu vaccine used in adults is not live
- Chicken pox vaccine, which is called varicella
- BCG vaccine against tuberculosis, or TB
- Yellow fever vaccine
- Oral typhoid vaccine: the injected typhoid is not live

#### If someone that you live with is due to have a live vaccine

There is a small risk that people who have received live vaccines could pass on the weakened form of the virus to close contacts who are immunosuppressed. This could then cause an infection. For most of the live vaccines used in the UK, the virus is not passed on to contacts. You can reduce the risk by following simple precautions, such as: washing your hands after direct contact with the person who has had the vaccine, and before preparing food.

# **Pregnancy and fertility**



## **Fertility**

The effect of etrasimod on fertility has not been studied. In animal studies, no effects on fertility were seen.

## **Planning a pregnancy**

Etrasimod should not be used during pregnancy as it can harm the unborn baby. Etrasimod should not be given to people who can become pregnant unless they are on effective contraception.

If you can become pregnant, your IBD team should talk to you about the risks of becoming pregnant while taking etrasimod. Your IBD team will also ask for a negative pregnancy test before starting etrasimod. You will need to use effective contraception while taking etrasimod. You must continue to use effective contraception for at least 14 days after you stop taking etrasimod. When starting etrasimod, you should be given a patient card. This card explains important information about pregnancy and etrasimod.

Do not stop taking your medicine without talking to your doctor first.

### If you have an unplanned pregnancy

Tell your doctor straight away if you become pregnant while taking etrasimod. It is likely that etrasimod will need to be stopped and checks performed on your unborn baby.

You might find our information on pregnancy and reproductive health useful.

# **Breastfeeding**

Etrasimod should not be used during breastfeeding. This is because there is not enough research to say if it's safe for your baby. Some animal studies have shown that etrasimod could be passed on via breast milk. It is not known whether etrasimod is present in human breast milk



We have more information on breastfeeding in our <u>pregnancy and breastfeeding</u> resource.

## **Drinking alcohol**

There is not currently any evidence on whether it is safe to drink alcohol while taking etrasimod. Talk to your IBD team about the risks of drinking alcohol while taking etrasimod.

## Who to talk to if you are worried

Taking medicines and managing side effects can be difficult. We understand that and we're here to help. Our Helpline can answer general questions about treatment options and can help you find support from others with the conditions.

Your IBD team are also there to help. You can talk to them about your dosage, how they'll be monitoring you and what alternatives may be available. You should also get in touch with your IBD team if you have any new symptoms or side effects.

It can take time to find the medicine that's right for you. Do not be afraid to ask questions and seek out extra support when you need it.

This information is general and does not replace specific advice from your health professional. Talk to your doctor or IBD team for more information.

#### **About this information**

We follow <u>strict processes</u> to make sure our award-winning information is based on up-todate evidence and is easy to understand. We produce it with patients, medical advisers



and other professionals. It is not intended to replace advice from your own healthcare professional.

We hope that you've found this information helpful. Please email us at <a href="mailto:evidence@crohnsandcolitis.org.uk">evidence@crohnsandcolitis.org.uk</a> if:

- You have any comments or suggestions for improvements
- You would like more information about the evidence we use
- You would like details of any conflicts of interest

You can also write to us at Crohn's & Colitis UK, 1 Bishop Square, Hatfield, AL10 9NE. Or you can contact us through our <u>Helpline</u> by calling **0300 222 5700**.

We do not endorse any products mentioned in our information.

## Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our award-winning information covers a wide range of topics. From treatment options to symptoms, relationship concerns to employment issues, our information can help you manage your condition. We'll help you find answers, access support and take control.

All information is available on our website at <a href="mailto:crohnsandcolitis.org.uk/information">crohnsandcolitis.org.uk/information</a>.

### **Helpline service**

Our <u>Helpline</u> team provides up-to-date, evidence-based information. They can support you to live well with Crohn's or Colitis.

Our Helpline team can help by:

- Providing information about Crohn's and Colitis
- Listening and talking through your situation
- Helping you to find support from others in the Crohn's and Colitis community

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Providing details of other specialist organisations

You can call the Helpline on **0300 222 5700**. You can also visit <a href="mailto:crohnsandcolitis.org.uk/livechat">crohnsandcolitis.org.uk/livechat</a> for our LiveChat service. Lines are open 9am to 5pm, Monday to Friday, except English bank holidays.

You can email <a href="mailto:helpline@crohnsandcolitis.org.uk">helpline@crohnsandcolitis.org.uk</a> at any time. The Helpline will aim to respond to your email within three working days.

#### **Crohn's & Colitis UK Forum**

This closed-group Facebook community is for anyone affected by Crohn's or Colitis. You can share your experiences and receive support from others at <a href="mailto:facebook.com/groups/CCUKforum">facebook.com/groups/CCUKforum</a>.

### Help with toilet access when out

There are many benefits to becoming a member of Crohn's & Colitis UK. One of these is a free RADAR key to unlock accessible toilets. Another is a Can't Wait Card. This card shows that you have a medical condition. It will help when you are out and need urgent access to the toilet. See <a href="mailto:crohnsandcolitis.org.uk/membership">crohnsandcolitis.org.uk/membership</a> for more information. Or you can call the Membership Team on 01727 734465.

### Crohn's & Colitis UK Medicine Tool

Our <u>Medicine Tool</u> is a simple way to compare different medicines for Crohn's or Colitis. You can see how medicines are taken, how well they work, and what ongoing checks you need.

The Medicine Tool can help you:

- Understand the differences between types of medicines
- Explore different treatment options



Feel empowered to discuss medicine options with your IBD team

Always talk to your IBD team before stopping or changing medicines.

### About Crohn's & Colitis UK

Crohn's & Colitis UK is a national charity, leading the fight against Crohn's and Colitis. We're here for everyone affected by these conditions.

Our vision is to see improved lives today and a world free from Crohn's and Colitis tomorrow. We seek to improve diagnosis and treatment, fund research into a cure, raise awareness and give people hope and confidence to live freer, fuller lives.

Our information is available thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis by calling **01727 734465**. Or you can visit <u>crohnsandcolitis.org.uk</u>.

#### About our information

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